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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,380	07/25/2002	Aharon Shulov	24871	9209

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EXAMINER

WINSTON, RANDALL O

ART UNIT PAPER NUMBER

1655

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,380

Applicant(s)

SHULOV ET AL.

Examiner

Randall Winston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/16/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 5-8-18 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 8-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of the receipt and entry of the amendment filed on August 16, 2005.

The rejection made under 35 U.S.C. 112, second paragraph have been overcome by Applicant's amendment.

The rejection made under 35 U.S.C. 102(e) have been overcome by Applicant's amendment.

Examiner acknowledges that claims 6 and 7 have been cancelled and claim 4 is withdrawn from consideration.

Claims 1-3, 5, 8-18 will be examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 8-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Politi et al. (US 6,057,297).

Applicant argues whereas the '297 patent relates to enzyme inhibitors (see, col 5) the claimed fraction comprises a metalloproteinase enzyme obtained from snake venom. The synthetic peptidomimetic compounds of the '297 patent are neither non-toxic nor do they have analgesic activity evidenced after a lag period. Moreover, the

'297 patent fails to contain a description or suggestion that would lead an artisan to the presently claimed product and method of use.

Applicant's argument are not found persuasive because claims 1-3, 5, 8, 8-18 stand rejected under 35 U.S.C. 103(a) for the reasons set forth in examiner's non final office action of 06/02/2005. As Examiner stated in his office action of 06/02/2005, Politi teaches the claimed fraction as well as the claimed fraction being non-toxic and having analgesic activity after a lag period because the product in the Politi appears to be the same. In this case, the Politi's product appears to be the same because it is a non-toxic venom product purified using ion-exchange chromatography that has pharmaceutical activity that relates to pain relief. Thus, Politi et al. teach (see, e.g., example 8, column 4 lines 14-18, column 3 line 52-55) applicant's claimed fraction for use as an analgesic to relieve pain (i.e. applicant please note again that Politi et al. teach that it's pharmaceutical composition treats inflammatory diseases whereas pain is associated with inflammation) comprising a substantially non-toxic fraction (i.e., applicant please note again Politi et al.'s pharmaceutical composition can be taken orally, therefore, one of ordinary skill in the art would not expect a substantially toxic substance to be taken orally) isolated from snake venom having the characteristics of a fraction purified by ion-exchange chromatography (i.e. by the ion-exchange column of a DEAE Sephadex A-50 resin) and eluting the fraction with an aqueous buffer (i.e. buffer is NaCl), wherein Politi's non-toxic purified fraction would also intrinsically have an analgesic effect after a lag period when administered, and wherein said snake family of isolated snake venom

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is also from *Crotalus adamanteus* in combination with a pharmaceutical acceptable carrier.

Politi et al. do not expressly teach its purification method is performed by the claimed invention's purification method of Mono Q ion-exchange chromatography and the topical administration and/or the parenteral administration of the claimed non-toxic purified fraction and eluting the fraction with buffers such as the Tris-HCL buffer or the ammonium acetate buffer. However, based upon the overall beneficial teachings provided by Politi et al, the result-effective adjustment of conventional working conditions therein (e.g., the substitution of one ion-exchange column for another ion-exchange column for the same purpose of achieving a purified fraction and the topically and/or the parenteral administration of said fraction and the substitution of one functionally equivalent buffer for another), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan D. Coe
11-7-05
SUSAN COE
PRIMARY EXAMINER